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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/30/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,586

Applicant(s)

MILLHAUSER ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

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DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached titled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 is mailed herewith. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, claim 4 and elsewhere. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks SEQ ID Nos cited along with each sequence in the claims. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy, or CD-ROM for the claims and elsewhere, statements under 37 CFR § 1.821 (f) and (g). Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 and 68-69, drawn to a method of modulating activity of a melanocortin receptor, classified in class 514, subclass 2. If this Group is elected, then the below summarized specie election is also required.
- II. Claims 19-31, drawn to a library for screening for modulators of a melanocortin receptor, classified in class 530, subclasses 300 and 350. If this Group is elected, then the below summarized specie election is also required.
- III. Claims 32-38 and 45-59, drawn to method of prescreening and screening for a modulator of a melanocortin receptor, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized specie election is also required.
- IV. Claims 39-44, 66-67, and 70, drawn to a polypeptide, classified in class 530, subclasses 300 and 350. If this Group is elected, then the below summarized specie election is also required.
- V. Claims 60-64, drawn to a machine-readable data storage medium, classified in class 211, subclass 41.12. If this Group is elected, then the below summarized specie election is also required.
- VI. Claim 65, drawn to an NMR structure, classified in class 424, subclass 9.3. If this Group is elected, then the below summarized specie election is also required.
- VII. Claims 71-83, drawn to a non-peptide melanocortin receptor ligand and its pharmaceutical preparation, classified in classes 424, subclass 1.45. If this Group is elected, then the below summarized specie election is also required.

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VIII. Claims 84-86, drawn to a method for modulating a melanocortin receptor mediated physiological process, classified in class 514, subclass 1. If this Group is elected then the below summarized specie election is also required.

Specie Election Requirement for Groups I-VIII:

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Group I:

Specie A: Modulation of melanocortin receptor during disease treatment

Specie B: Modulation of melanocortin receptor without disease treatment being performed

For Groups I-VIII:

Specie A: a specific polypeptide structure

Specie B: a specific non-peptide structure

Please note if Group II is elected then applicants may choose two specific polypeptides as the libraries at least contain a plurality of polypeptides.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims in Group I-VIII are generic to the above species. This distinctness or independence of a modulation during disease treatment versus modulation without disease treatment performed (Group I) as well as a

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specific polypeptide versus a specific non-peptide structure (Groups I-VIII) is because all of these species are directed to different chemical and/or entity types regarding the critical features therein. For the receptor modulation during disease treatment specie, the critical feature is disease treatment. For the receptor modulation with treatment, the critical feature is no disease treatment. For the polypeptide structure specie, the critical feature is a polypeptide. For a non-peptide structure specie, the critical feature is a non-peptide. The completely separate chemical and entity types of the species are often separately characterized and published in literature, thus adding to the search burden if all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the above-mentioned species are independent and/or distinct specie types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groupings [I and IV], [II and III], [V], [VI], and [VII and VIII], are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I and IV, the critical feature is a modulation method utilizing a peptide. For Groups II and III, the critical feature is a library. For Group V, the critical feature is a machine-readable data storage medium. For Group VI, the critical feature is an NMR structure. For Group VII and VIII, the critical feature is a non-peptide melanocortin receptor ligand. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the five

Groupings [I and IV], [II and III], [V], [VI], and [VII and VIII] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I and IV are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide of Group IV may be utilized in distinct usages as needed in Group I for a method of modulating activity of a melanocortin receptor, or alternatively, in making antibodies or cell growth inhibition studies. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups II and III are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the library of Group II may be utilized in distinct usages as needed in Group III for a method of prescreening and screening for a melanocortin receptor modulator, or alternatively, in gene mapping studies. All of these usages are distinct as requiring distinct and different

functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups VII and VIII are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the non-peptide ligand of Group VII may be utilized in distinct usages as needed in Group VIII for a method of modulating a melanocortin receptor mediated physiological process, or alternatively, in cell growth inhibition studies. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 9 A.M. to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 28, 2002

Andie H. March
Technical Center 1600